K103678 1/3

FEB 16 2011

GE Healthcare

510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: March 30, 2010

Submitter: GE Healthcare, GE Medical Systems Information Technologies GmbH
Munzinger Strasse 5
79111 Freiburg , Germany

Primary Contact Person: Albrecht Malkmus
Regulatory Affairs - Diagnostic Cardiology
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Secondary Contact Person: Doug Kentz
Regulatory Affairs - Diagnostic Cardiology
GE Healthcare, GE Medical Systems Information Technologies, Inc.
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Milwaukee, WI 53223
Phone: (414) 581-8987
Fax: (414) 362-2585

Device: Trade Name: CASE Cardiac Testing System
CS Cardiac Testing System

Common/Usual Name: ECG Analysis Computer

Classification Names: 2 1 CFR 870.1425 Programmable diagnostic computer

Product Code: DQK

Predicate Device(s): CardioSoft / CASE Cardiac Testing System K031561

Device Description: The CASE Cardiac Testing System and the CS Cardiac Testing System are designed to be used for resting ECG, stress test ECG, Spirometery, Ambulatory Blood Pressure and for recording ECG in real-time with and without arrhythmia detection. The CS Cardiac

Testing System will be offered as a software only package including a front end for data acquisition. The CASE Cardiac Testing System is a turnkey product utilizing the CS Cardiac Testing software. CASE Cardiac Testing System and the CS Cardiac Testing System are intended to be used by trained operators under direct supervision of a licensed health care practitioner on adult and pediatric patients. The CASE Cardiac Testing System and the CS Cardiac Testing System are designed to acquire, process, record, archive, analyze and output (12 and 15 lead) ECG data during a period of physiologic stress or during a resting ECG test, acquire data from ancillary devices (such as Spirometry and Ambulatory Blood Pressure), provide median morphology recordings and record ECG in real-time with and without arrhythmia detection. The arrhythmia detection portion of CASE Cardiac Testing System and the CS Cardiac Testing System are provided to the user for the convenience of automatic detection of arrhythmias but does not provide alarms. The CS Cardiac Testing System was formerly named Cardiosoft.

Intended Use:

CASE Cardiac Testing System and the CS Cardiac Testing System are intended to be used by trained operators under direct supervision of a licensed health care practitioner on adult and pediatric patients. The CASE Cardiac Testing System and the CS Cardiac Testing System are designed to acquire, process, record, archive, analyze and output (12 and 15 lead) ECG data during a period of physiologic stress or during a resting ECG test, acquire data from ancillary devices (such as Spirometry and Ambulatory Blood Pressure), provide median morphology recordings and record ECG in real-time with and without arrhythmia detection. The arrhythmia detection portion of CASE Cardiac Testing System and the CS Cardiac Testing System are provided to the user for the convenience of automatic detection of arrhythmias but does not provide alarms.

CASE Cardiac Testing System and the CS Cardiac Testing System provide the control of external devices (typically a treadmill or Ergometer) and communicate with centralized electronic/digital storage system via network. CASE Cardiac Testing System and the CS Cardiac Testing System provide a user selectable option for printouts of prognostic scores on select reports. Vector loops are also available.

CASE Cardiac Testing System and the CS Cardiac Testing System can be configured in a network environment for multiple CASE or CS stations allowing the user to create a central database of patient demographics and collected patient physiological data.

CASE Cardiac Testing System and the CS Cardiac Testing System are intended to be used primarily in the hospital but can be used in clinics, physician offices, outreach centers or wherever exercise, stress testing, ECG, Spirometry or ambulatory blood pressure testing

is performed.
CASE Cardiac Testing System and the CS Cardiac Testing System offer no diagnostic opinion to the user. Instead it provides interpretive statements of morphology, rhythm, and conduction for which the physician renders his/her own medical opinion.
CASE /CS Cardiac Testing System is not intended to be used as a transport device or for home use. CASE Cardiac Testing System and the CS Cardiac Testing System are not intended for the use as a vital signs physiological monitor or for intracardiac use. The CS Cardiac Testing System was formerly named Cardiosoft.

Technology: The proposed CASE Cardiac Testing System and the CS Cardiac Testing System employ the same technology as the predicate device CardioSoft /CASE Cardiac Testing System (K031561)

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The CASE Cardiac Testing System and the CS Cardiac Testing System and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, CASE Cardiac Testing System and the CS Cardiac Testing System did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the CASE Cardiac Testing System and the CS Cardiac Testing System to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

GE Medical Systems Information Technologies
c/o Mr. Albrecht Malkmus
Regulatory Affairs Leader
3200 N Grandview Boulevard
Waukesha, WI 51388

FEB 16 2011

Re: K103678
Trade/Device Name: CASE V6.6 and CS V6.6 Cardiac Testing Systems
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer.
Regulatory Class: Class II (two)
Product Code: DQK
Dated: March 30, 2010
Received: December 16, 2010

Dear Mr. Malkmus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

GE Healthcare
510(k) Premarket Notification Submission

510(k) Number (if known):

Device Names:

CASE Cardiac Testing System
CS Cardiac Testing System

Indications for Use:

The CASE Cardiac Testing System and CS Cardiac Testing System are designed to be used for resting ECG, stress test ECG, Spirometery, Ambulatory Blood Pressure and for recording ECG in real-time with and without arrhythmia detection. The CASE is a turnkey product utilizing the CS software. The CS will be offered as a software only package including a front end for data acquisition.
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CASE Cardiac Testing System and CS Cardiac Testing System are intended to be used primarily in the hospital but can be used in clinics, physician offices, outreach centers or wherever exercise, stress testing, ECG, Spirometry or ambulatory blood pressure testing is performed.

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Prescription Use_X___ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103678